

Reply Brief Under 37 C.F.R. § 41.41(a)

Application No. 10/664,715

Paper Dated: September 30, 2011

In Reply to USPTO Correspondence of August 1, 2011

Attorney Docket No. 3896-113343 (P-5808/1)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application No. : 10/664,715 Confirmation No. 4404  
Appellants : DIMITRIOS MANOUSSAKIS et al.  
Filed : September 18, 2003  
Title : HIGH BIAS GEL TUBE AND PROCESS FOR  
MAKING TUBE  
Group Art Unit : 1773  
Examiner : Patricia Kathryn Wright

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Commissioner for Patents

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Alexandria, VA 22313-1450

**REPLY BRIEF TO EXAMINER'S ANSWER PURSUANT TO 37 C.F.R. § 41.41(a)**

Sir:

In further support of the Appeal Brief filed on May 31, 2011, and in response to the Examiner's Answer mailed on August 1, 2011, Appellants submit this Reply Brief under 37 C.F.R. § 41.41(a). A Request for Oral Hearing is concurrently submitted herewith.

I hereby certify that this correspondence is being electronically  
submitted to the United States Patent and Trademark Office on  
September 30, 2011.

09/30/2011

Date

*Sharyn Beck*

Signature

Sharyn Beck

Typed Name of Person Signing Certificate

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### **STATUS OF CLAIMS**

Claims 14, 16-18, 20-24, 26-28, and 30-32 are currently pending with claims 1-13, 33-60, and 67-86 withdrawn and claims 15, 19, 25, 29, and 61-66 cancelled. Claim 14 is an independent claim.

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### **GROUND OF REJECTION TO BE REVIEWED**

Claims 14, 16-18, 20-24, 26-28, and 30-32 stand finally rejected under 35 U.S.C. § 103(a) for obviousness over European Patent No. EP 1 107 002 to Conway (hereinafter "Conway"). The Examiner also relies on United States Patent No. 4,101,422 to Lamont (hereinafter "Lamont").

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### ARGUMENT IN REPLY

As an initial matter, Appellants would like to focus the Board's attention on the true innovation disclosed in the current application, namely the precise positioning and geometry of the thixotropic gel within the container. As is clearly set forth in the specification (for example, at paragraphs [0018] and [0019]), in the Manoussakis Declaration, and throughout the prosecution history, the precise geometry of the gel of the present invention overcomes gel movement by exhibiting a geometric state similar to a gel at an intermediate state of centrifugation. Appellants have incorporated specific claim coverage to define the specific geometry of the gel. Despite such specific claim features, the Examiner relies on the patent to Conway, and the disclosure within Conway of prior gels used without a deformable container, or bag. The Examiner, however, simply ignores the fact that neither Conway nor any of the cited references include any disclosure, teaching, or suggestion that positioning the gel within the container according to certain parameters based on a geometry relating to an intermediate state of centrifugation provides optimal separation of fluid during centrifugation. The current application discloses that specific volumes of gel positioned with precise geometries in each of the regions can optimize separation during centrifugation. Conway is silent with respect to the geometric positioning of gel, let alone as to whether the positioning of the gel affects centrifugation in any way. The invention described in the current application achieves optimal separation due to the initial geometric positioning of the gel, as claimed, which is comparable to the transient state (i.e. mid-centrifuge). *See* paragraph [0016]. In contrast, the positioning of the gel in Conway is not described in any specific terms in either the specification or the figures, as discussed *infra*.

#### **I. Claims 14, 16-18, 20-24, 26-28, and 30-32 are not rendered obvious by Conway.**

As mentioned above, claims 14, 16-18, 20-24, 26-28, and 30-32 stand finally rejected under 35 U.S.C. § 103(a) for obviousness over Conway. In view of the following remarks, the Appellants continue to request reversal of this rejection.

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**A. The Examiner's Answer fails to show that Conway discloses a first region of the gel that comprises at least about 80 vol. % of the gel.**

Unlike the presently claimed invention of independent claim 14, Conway does not disclose a first region of the thixotropic gel that comprises at least about 80 vol. % of the gel. Conway discloses a deformable container, or bag, filled with thixotropic gel that is positioned within a collection tube. The collection tube and bag are formed such that the gel fills only a portion of the bag, leaving a portion of the bag "substantially absent of gel". *See* Conway, paragraph [0028]. Conway neither discloses a percentage of gel that constitutes "substantially absent" nor provides drawings that are to scale, precluding any reasonable analysis of the meaning of "substantially absent". The Examiner admits that Conway does not provide drawings that are to scale and does not disclose values for "substantially absent". *See* Examiner's Answer, page 11. In contrast, the current claims specify a gel geometry with a defined volume that optimizes the flow of the gel during centrifugation. *See* paragraphs [0016], [0022]. Despite this clear difference, and lack of disclosure in Conway, the Examiner asserts that "it can be reasonably assumed" that the portion of the bag of Conway that is not "substantially absent" of gel comprises "at least about 80 vol. % of the thixotropic gel". *See* Examiner's Answer, page 5.

The Examiner's Answer ignores the established principle that a finding of obviousness must be accompanied by an "articulated reason with some rational underpinning." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). The Examiner asserts that under MPEP 2125, "the description of the article pictured can be relied on, in combination with the drawings, for what they would reasonably teach one of ordinary skill in the art." *See* Examiner's Answer, page 11. However, it is improper to rely on drawings that are not to scale and a disclosure that does not provide amounts or percentages to "reasonably assume" that a given claim limitation recited in the current application is rendered obvious. *Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956 (Fed. Cir. 2000) ("[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.") (citations omitted). Moreover, the instant case is distinguishable from that

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of *In re Macove*, where this Board found that despite a specification that was silent on the issue of scale, Figure 1 of the prior art reference in that appeal, “provide[d] an important clue that the drawing is intended to accurately represent the configuration of the device.” *In re Macove*, 2011 Pat. App. LEXIS 14904, at \*16 (BPAI Feb. 25, 2011). Here, there is no indication from the specification or figure legends that any of the figures from Conway are intended to accurately represent the geometric configuration of the gel within the container. On the other hand, the precise geometry of the gel including the specific claimed volume in the first region achieves features that are not even contemplated in Conway, namely, avoidance of gel movement and effective sample separation based on gel geometry. Accordingly, a motivation to require a certain percentage of gel in a given region of the container has not been shown, and a showing of obviousness based on Conway cannot be supported.

**B. The Examiner’s Answer fails to show a proper motivation to modify Conway or reasonable expectation of success with said modification.**

Unlike the presently claimed invention of independent claim 14, and as admitted in the final Office Action and Examiner’s Answer, Conway does not disclose a container with a thixotropic gel in contact with a portion of the inner wall of the container. See Examiner’s Answer, page 5. Rather, Conway discloses a deformable container, or bag, within which the thixotropic gel is contained, the bag residing inside a collection tube. The Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time to modify Conway by eliminating the bag from the collection tube for two reasons.

First, the Examiner asserts that Conway discloses that, “the use of thixotropic gel materials as a direct barrier for moving into an area adjacent the two phases of the sample being separated...is well known in the art.” See Examiner’s Answer, page 5. Conway, however, teaches that the nature of thixotropic gels limits their application in prior containers because the gels may release unbound resin into the surrounding fluid, leading to obstructions in instruments used to measure analyte levels in the fluid. See Conway, paragraph [0004]. Conway also discloses that “no commercially available gel is completely chemically inert to all analytes.” See

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Conway, paragraph [0005]. Thus, despite the fact that Conway teaches that using a thixotropic gel without a containment bag may impair analysis equipment, and in the event that no impairment is done, may result in erroneous analyses of the fluid sample, the Examiner asserts that one of ordinary skill in the art would be motivated to eliminate the bag because the bag increases “manufacturing cost and complexity of the device”. See Examiner’s Answer, page 6.

The Examiner further asserts that eliminating the bag from the container would “not prevent the thixotropic gel in Conway from readily flowing at lower centrifugation speeds and establishing a physical separation between the phases of blood sample” because the use of such gels was known in the art. This assertion is incorrect in two ways. First, gel flowing inside of a deformable container would necessarily have different movement characteristics than gel that is not so constrained, and a conclusory statement to the contrary, without any factual support, is in direct conflict with the instructions from the Supreme Court. *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. at 418. Second, the Examiner’s assertion does not address the differences between Conway and the currently claimed invention, namely the specific positioning and geometry of the gel in the claimed invention. Further, the Examiner ignores the possibility of interference with both the analysis machine and the results of the analyses themselves. Quite simply, the present claims define a gel in contact with a container wall, and Conway specifically and unequivocally teaches away, by placing the gel in a bag, thereby avoiding direct contact with the container wall.

With regard to such positioning of the gel, the Examiner further makes a conclusory statement that the positioning in Conway “promotes initiation of flowable separation medium movement”. See Examiner’s Answer, page 8. The Examiner, however, provides no support for that assertion, as required for a showing of obviousness. *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. at 418. Moreover, Conway fails to disclose that the initial positioning of the gel in the tube promotes or hinders the flow of the gel during centrifugation, or that initial positioning is a factor in gel movement. In contrast, the current application discloses a precise range of volumes and geometries for the initial positioning of the gel in order to best avoid gel movement issues. See paragraphs [0018], [0021] – [0032].

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With regard to the possible unwanted interactions between the gel and the fluid sample or the analysis machines, the Examiner points to the citation in the current application of United States Patent 4,101,422 to Lamont as evidence that modifying Conway would not result in these unwanted characteristics. *See* Examiner's Answer, page 10. Examination of Lamont, however, reveals only that Lamont discloses that the polyester compositions "are not affected by contact with the blood and they do not alter the blood components." *See* Lamont, col. 2, lines 31-33. No mention is made of interactions between the gel and chemicals present in the blood sample that are not themselves components of blood, nor of the possibility that gel resin will enter the fluid to be analyzed and thus impair the function of the analysis machines.

Far from supporting the rejection for obviousness with the articulated reasoning demanded by the Supreme Court in *KSR*, the Examiner proposes modifications to Conway that would render the container disclosed therein unsuitable for its intended purpose. Such a proposed modification is contrary to the direction of the Court of Appeals for the Federal Circuit, and in effect teaches away from the current container. *See In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984). Accordingly, a motivation to eliminate the deformable bag of Conway has not been shown, and a finding of obviousness based on Conway therefore cannot be supported. Appellants respectfully request that the rejection of claim 14 as obvious over Conway under 35 U.S.C. § 103(a) be reversed.

**C. The Examiner's Answer fails show a proper motivation to modify the geometry of the gel of Conway.**

The Examiner asserts that dependent claims 16-18, 20-24, 26, and 27 are obvious in view of Conway for a number of reasons that do not meet the standard elucidated by the Supreme Court in *KSR*. For example, Conway does not disclose, teach, or suggest any of the limitations recited in claims 16-18, 20-24, 26, and 27 or of the potential advantage of said limitations of the current application. As such, the Examiner relies on assumptions for which there is no support in Conway.



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The Examiner states with regard to claim 16 that “it appears the imaginary upper boundary of Conway exhibits a best fit plane within 10 degrees of a plane perpendicular to the longitudinal axis of the tube”. *See* Examiner’s Answer, page 6. As discussed *supra*, drawings that are not to scale, in combination with a specification that is silent as to scale, measurement, or geometry, cannot be relied upon to show particular sizes. *Hockerson-Halberstadt, Inc. v. Avia Group Int’l*, 222 F.3d at 956. Further, unlike the current application, Conway makes no effort to describe a best fit plane in relation to the thixotropic gel. Examination of the specification and figures from Conway reveals that there is no indication that a best fit plane is contemplated or considered relevant, whereas the specification, specifically paragraph [0024], and the figures, specifically Fig. 4, of the current application disclose specific criteria for the best fit plane to overcome gel movement issues.

The Examiner further asserts that claims 17 and 18 are obvious in view of Conway because the distance between the uppermost points of the first and second regions of the thixotropic gel in the container is between 8-21 mm, because, “the claimed distance would have been obvious to one of ordinary skill in the art through routine experimentation in an effort to optimize the operational parameters of the device”. *See* Examiner’s Answer, page 6. Again, the Examiner fails to provide a rational underpinning to support this conclusion of obviousness. Conway provides insufficient basis to achieve the claimed measurements, and thus cannot support a finding of obviousness. *See Ex parte Min-Chul San*, 2011 Pat. App. LEXIS 14070, at \* 6-7 (BPAI Mar. 2, 2011) (the Board reversed a rejection based on obviousness because the cited reference gave “insufficient basis to achieve the claimed [claim limitation].”). Conway does not disclose a distance between the uppermost points of the first and second regions of thixotropic gel. In fact, Conway fails to disclose, teach, or even suggest that the distance is a factor in minimizing gel movement issues, let alone optimization of results. In contrast, the specification, specifically paragraphs [0018] and [0021], and the figures, specifically Fig. 3, of the current application disclose specific criteria for the distance between the uppermost points of each gel region to overcome gel movement issues. As such, Appellants respectfully request that the rejection of claims 16-18 as obvious over Conway under 35 U.S.C. § 103(a) be reversed.

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The Examiner rejects claims 20-24 because “it is reasonable to assume” that the first region of the gel in Conway comprises the specific measurements and geometry of the current application. *See* Examiner’s Answer, page 6. As discussed previously, the figures in Conway are not to scale, and the specification is silent on the issue. *Halberstadt, Inc. v. Avia Group Int’l*, 222 F.3d at 956. Further, there is no indication that the figures in Conway are intended to accurately represent the container. *In re Macove*, 2011 Pat. App. LEXIS 14904, at \*16. In contrast, the present application discloses in paragraphs [0022] - [0025] gel volumes and geometries for the first region and best fit planes for the exposed surfaces of each region relative to the longitudinal axis of the container. As such, the Examiner’s rejection is nothing more than a mere conclusory statement without an articulated reason or factual support, and cannot be sustained. *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. at 418. Appellants respectfully request that the rejection of claims 20-24 as obvious over Conway under 35 U.S.C. § 103(a) be reversed.

The Examiner lastly asserts that claims 26 and 27 are obvious in view of Conway because “Conway exhibits 80 to 140° circumferential contact with the inner surface, wherein the entirety of the second region exhibits less than 180° circumferential contact with the inner wall 15a and, wherein the entirety of the second region 22a exhibits less than 120° circumferential contact with the inner wall 15a, see in particular Figs. 1 and 2 of Conway.” *See* Examiner’s Answer, page 7. As discussed previously, the figures in Conway are not to scale, and the specification is silent on the issue. *Halberstadt, Inc. v. Avia Group Int’l*, 222 F.3d at 956. Further, there is no indication that the figures in Conway are intended to accurately represent the container. *In re Macove*, 2011 Pat. App. LEXIS 14904, at \*16. Moreover, there is no means by which one of ordinary skill in the art might view Figs. 1 and 2 of Conway and determine the degree of circumferential contact between the second region and the inner wall of the container. It is true that the Examiner may take into account not only the specific teachings of a reference, but also reasonable inferences to be taken therefrom. *In re Preda*, 401 F.2d 825, 826 (CCPA 1968) (citing *In re Shepard*, 319 F.2d 194 (CCPA 1963)). However, in the current appeal, the figures and specification of Conway do not provide any reasonable basis from which one of ordinary skill in the art might arrive at a circumferential contact of 80 to 140°. Neither the

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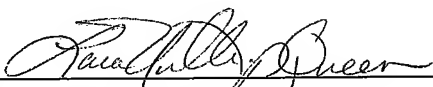
specification nor figures in Conway disclose a degree of circumferential contact, nor does Conway teach that a certain range of degrees is important for minimizing gel movement issues. In contrast, Figs. 6 and 7 and paragraphs [0026] and [0027] of the current application disclose specific ranges of circumferential contact between the gel and the inner wall of the container. As such, the Examiner has not met her burden for proving a *prima facie* case of obviousness, and Appellants respectfully request that the rejection of claims 26 and 27 as obvious over Conway under 35 U.S.C. § 103(a) be reversed.

## II. Conclusion

For the reasons set forth above, Appellants submit that claims 14, 16-18, 20-24, 26-28, and 30-32 are patentable over the cited art and are in condition for allowance. Reversal of all of the Examiner's rejections and allowance of these claims are therefore respectfully requested.

Respectfully submitted,

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